



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES  
Antimicrobials Division

May 2, 2005

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: T99-19 (40%)

DP Barcode: D305003  
Manufacturing-use [ ] OR

Reg. No. Or File Symbol: 3090-EEN  
End-use Product [X]

TO: Velma Noble PM 31 / Tracy Lantz, Team Reviewer  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

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*K. P. Hicks*  
5/5/05

**Product Formulation**

Active Ingredient(s)	% by wt.
Dimethyl tetradecyl-[3-(trimethoxysilyl)-propyl]	
ammonium chloride .....	40.0

**BACKGROUND:** The applicant has submitted an application for registration of a pesticide product having a new active ingredient. This submission is a resubmission to overcome certain deficiencies and data gaps noted in the Agency's letters dated March 1, 2004, and May 13, 2004. In support of the

reaction and post-reaction process of producing the subject pesticide product and studies responding to the requirements of OPPTS Test Guidelines Series 830, Groups A & B.

#### **FINDINGS:**

1. The CSF (Post-Reaction) of the subject product is not acceptable to the Agency. The formulation has a second quaternary ammonium compound at a concentration of 3.5% that is undeclared as an active ingredient. Quaternary ammonium chlorides, as a class, are generally active antimicrobial chemicals. In the current formulation the tetradecyl trimethyl ammonium chloride constitutes a significant percent of the composition and must be declared as a second new active ingredient.
2. The data points developed in response to the requirements of OPPTS Test Guidelines Series 830 Group B were not determined under conditions of GLP.

#### **RECOMMENDATIONS:**

1. The applicant must declare the second quaternary ammonium compound, tetradecyl trimethyl ammonium chloride, as an active ingredient and submit to the Agency a full disclosure of the physical/chemistry data required for the acceptance of a new active ingredient.
2. The applicant must describe the materials used to produce the product according to the guideline, 830.1600.
3. The applicant must, under conditions of GLP, respond to the requirements of 830.7000, -7220, -6315, -7100, -6319, and -6320.

**PRODUCT CHEMISTRY REVIEW**

4. **CONFIDENTIAL STATEMENT OF FORMULA**

4a. Type of formulation and source registration

- Non-integrated formulation system ☐
- Are all TGAs used registered? Yes ☐ No ☐
- Integrated formulation system ☒
- if "ME-TOO", specify EPA Reg. # of existing product:

4b. Clearance of inerts for non-food or food use:

Cleared for food use under 40 CFR §180.1001: Yes ☐ No ☐ NA ☒

4c. Physical state of product: Liquid

4d. The chemical IDs and analytical information (including that for the TGAs), density, pH, and flammability are consistent with that given in 830, Part B  
Yes ☐ No ☒

4h. NCs and CLs are acceptable: Yes ☒ No ☐ Not acceptable ☐

4i. Active ingredient (s)	NC	LCL	UCL
Dimethyl tetradecyl-[3-(trimethoxysilyl)-propyl] ammonium chloride	40.0%	38.8%	41.2%

4j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have a UCL?  
Yes ☐ No ☐ Not applicable ☒
- All impurities of  $\geq 0.1\%$  in the product have been identified? Yes ☒ No ☐  
Not applicable ☐

5. PRODUCT LABEL

5a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes [X] No [ ]

5b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- Sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

5c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?  
Yes [ ] No [ ] Not applicable [X]

5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses?  
Yes [X] No [ ] Not on label

5f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information)?  
Yes [ ] No [X]

4. **PRODUCT CHEMISTRY (830 Series, Part A)**

Guideline	Acceptance of Information	MRID No.
830.1550 <sup>1</sup> Product Identity	A	462804-01
830.1600 Description of Materials	U	462804-01
830.1620 Production Method <sup>2</sup>	A	462804-01
830.1650 Formulation process <sup>3</sup>	NA	
830.1670 Formation of impurities <sup>4</sup>	A	462804-01
830.1700 Preliminary Analysis <sup>5</sup>	A	462804-03
830.1750 Certified Limits <sup>6</sup>	A	462804-01
830.1800 Analytical Method <sup>7</sup> - Titration	A	462804-01

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

<sup>1</sup>See Confidential Appendix A for additional information

<sup>2</sup>For MP/EP products produced by an integrated formulation system.

<sup>3</sup>For products from a TGAI or MP.

<sup>4</sup>May be waived unless actual/possible impurities are of toxicological concern.

<sup>5</sup>Five batch analysis required for products produced by an integrated formulation system.

<sup>6</sup>If different from standard CIs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

<sup>7</sup>Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

6b. <u>Physical/Chemical Properties</u> *	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	A	Yellowish, clear	462804-02
830.6303 Physical state	A	Liquid	462804-02
830.6303 Odor	A	Characteristic	462804-02
830.7200 Melting point	NA		
830.7220 Density/Relative density/bulk density	U	1.011 g/ml @ 20o C	462804-02
830.7000 pH <sup>1</sup>	U	6.9 @ 5% solution	462804-02
830.6314 Oxidation/Reduction	NA	Does not contain oxidizing/reducing agents	462804-02
830.6315 Flammability	U	Flash point = 161.6o F (72o C)	462804-02
830.6317 Storage stability	W		
830.7100 Viscosity	U	76 cP	462804-02
830.6319 Miscibility <sup>2</sup>	U	Miscible in methanol and other organic solvents	462804-02
830.6320 Corrosion Character.	U	Non-corrosive in plastic lined containers	462804-02
830.6321 Dielectric breakdown	A	Product not intended to be used around electrical equipment	462804-02

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

\* Provide brief description, e.g., color—yellow or property value, e.g., density 1.25 g/cc;

Unless otherwise indicated, the property should be at 25 °C.

<sup>1</sup> If product is dispersible with water

<sup>2</sup> If product is an emulsifiable liquid